



California State Board of Pharmacy
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STATE AND CONSUMER SERVICES AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

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**California State Board of Pharmacy
Department of Consumer Affairs
Notice of Public Board Meeting
October 24 and 25, 2007**

This board meeting is open to the public and is held in a barrier-free facility in accordance with the Americans with Disabilities Act. Any person with a disability who requires a disability-related modification or accommodation in order to participate in the public meeting may make a request for such modification or accommodation by contacting Karen Abbe at (916) 574-7946, at least five working days prior to the meeting.

Opportunities are provided to the public to address the board on each open agenda item.

Agenda

DATE: October 24 and 25, 2007

**PLACE: San Jose DoubleTree Hotel (near San Jose Airport)
2050 Gateway Place
San Jose, CA 95110
(408) 453-4000**

Note: Pharmacists and pharmacy technicians who attend the full day of the board meeting on Wednesday, October 24, 2007, may be awarded 6 hours of CE, in accordance with the board's CE policy.

Wednesday, October 24, 2007

CALL TO ORDER ***9:00 a.m.**

General Announcements

I. Committee Reports And Action

Each committee report contains an update to the board on the committee's recent activities and may include recommendations for board action. An opportunity for public comment is provided at the end of each report.

A. Enforcement Committee **9:05 a.m.**

1. Report and Action of Items Discussed at the Workgroup on E-Pedigree Subcommittee Meeting of September 20, 2007
2. Presentations to the Board on the Status of Electronic Pedigree Implementation
 - a. Alien Technology on the Status of RFID Technology
 - b. IBM/AmerisourceBergen Presentation on the EPCIS
 - c. EPCglobal Presentation on the Status of Standards Development for Electronic Pedigrees

****Times are approximate and are subject to change***

Meeting Materials will be available on the board's Web site at www.pharmacy.ca.gov by October 19, 2007

3. Meeting Summary and Discussion of a Board Subcommittee Review of EPCglobal's Electronic Pedigree Standard
4. Discussion and Action Regarding Implementation of Electronic Pedigree Requirements for Prescription Medicine in California

Public Comment

Break

5. Discussion and Action Report of the Enforcement Committee Meeting of September 20, 2007
 - a. Proposal to Develop an Ethics Course for Pharmacists, Modeled After That Developed by the Medical Board of California
 - b. Development of Self Assessment Forms for Veterinary Food Animal Drug Retailers
 - c. Review of the Modified Disciplinary Guidelines for the Board of Pharmacy
6. Requirements of the Center for Medicare and Medicaid Services to Use Security Prescription Pads for Prescriptions
7. Request and Action Regarding a Request from University Specialty Pharmacy to Waive Provisions Of 16 CCR 1717(e) for Betterment of Patient Care
8. Enforcement Statistics Report
9. First Quarterly Status Report on Committee Goals for 2007/08

Public Comment

Recognition of Pharmacists Licensed with the Board for 50 Years

11:30 a.m.

Lunch

B. Licensing Committee

1:00 p.m.

1. Report and Action of Items Discussed at the Licensing Committee Meeting of September 5, 2007
 - a. Proposed Regulation Requirements for Pharmacies that Compound Medication and Sterile Injectable Medication
 - Amendments to 16 CCR Sections 1716.1, 1716.2 and 1751 – 1751.8, and Adoption of Sections 1735-1735.8
 - b. Legislative Proposal: Immunizations by Pharmacists Pursuant to Published Recommendations of the Advisory Committee on Immunization Practices
 - c. Legislative Proposal: Licensing of Mobile Locations by the Board of Pharmacy for Emergencies
 - d. Update of Emergency Preparedness for California Pharmacy
 - e. California Schools of Pharmacy Proposal to Identify and Agree on the Professional Competencies that Should be Achieved by the End of Basic Internship Experiences
 - f. Update on the Request to Add the Exam for the Certification of Pharmacy Technicians as a Qualifying Method for Pharmacy Technician Registration
 - g. Competency Committee Report – Including the New Test Administration Company for the CPJE
 - (1) Examination Statistics: April 1 – August 31, 2007
 - (2) NAPLEX Compromised, Suspended, and Reactivated
 - (3) Proposed Amendment to 16 CCR Sections 1721 and 1723.1 Regarding Dishonest Conduct On a Pharmacist Licensure Examination
 - h. Creighton University's Web-Based PharmD Program
 - i. Meeting Summary of the September 5, 2007 Meeting
2. Licensing Statistics
3. First Quarterly Report on Committee Goals for 2007/08

Public Comment

C. Communication and Public Education Committee

2:00 p.m.

1. Discussion and Action on the Board's Proposed Public Forum on Medicare Prescription Drug Plans
2. Report and Action of Items Discussed at the Communication and Public Education Committee Meeting of September 14, 2007
 - a. Consumer Fact Sheet Series with California Pharmacist Interns and UCSF's Center for Consumer Self Care
 - b. Update Report on *The Script*
 - c. New Board Web Site Under Development
 - d. Development of New Consumer Brochures
 - e. National Council on Patient Information and Education's Medication Compliance Report
 - f. Update on Public Outreach Activities
3. Meeting Summary of the Meeting of September 14, 2007 Meeting
4. First Quarterly Report on Committee Goals for 2007/08

Public Comment

Break

D. Legislation and Regulation Committee

3:00 p.m.

Part 1: Regulation Report and Action

Note: CCR as used below means California Code of Regulations

1. **Regulations Submitted to the Administration for Approval**
 - a. Proposed Amendment of 16 CCR 1707.2 – Notice to Consumers
 - b. Proposed Amendment of 16 CCR 1749 – Fee Schedule
 - c. Section 100 Technical Changes
 - (1) Proposed Amendment to 16 CCR § 1709.1 – Replace the Term “Exemptee-in-Charge” with “Designated Representative-in-Charge”
 - (2) Proposed Amendment to 16 CCR § 1780.1 and 1781 – Replace the term “Exemptee” with “Designated Representative”
 - (3) Proposed Repeal of 16 CCR § 1786 – Return of Exemption Certificate
 - (4) Proposed Amendment to 16 CCR § 1715 – Self Assessment of a Pharmacy by the Pharmacist-in-Charge to Update for Changes in Pharmacy Law
 - (5) Proposed Amendment to 16 CCR § 1793.8 to Update Regulation Reference to Recodified Business and Professions Code § 4052
 - (6) Proposed Amendment to 16 CCR § 1707 Waiver Requirements for Off-Site Storage of Records
 - (7) Proposed Amendment to 16 CCR § 1787 Authorization to Distribute Dialysis Drugs and Devices
 - (8) Proposed Amendment to 16 CCR § 1790 Assembling and Packaging
 - (9) Proposed Amendment to 16 CCR § 1719 Pharmacy Practice
 - d. Addition to the California Building Code – 24 CCR 490A.3 and 505.12.2 Related to Compounding Parenteral Solutions: Technical Changes to the Building Code Relating to Pharmacies
4. **Board-Approved – Awaiting Public Notice**
 - a. Proposal to Require the Self Assessment of a Veterinary Food Animal Drug Retailer Premises, Addition of 16 CCR § 1785
 - b. Proposed Amendment to 16 CCR § 1760 – Disciplinary Guidelines
 - c. Section 100 Change: Update 16 CCR § 1780 – USP Standards Reference Material CCR
 - d. Proposed Regulation on the Process and Criteria to Approve Accreditation Agencies for Pharmacies that Compound Sterile Injectable Drug Products

Public Comment

Part 2: Legislation Report and Action

5. Board-Sponsored Legislation

Omnibus Provisions Contained in SB 1048

- (1) CURES Reporting – Dispense Schedule IV Drug to Emergency Room Patients – Amend Business and Professions Code § 4068
- (2) Authorize Board Inspectors to Embargo Misbranded Drugs – Amend Business and Professions Code § 4084
- (3) Correct “Exemptee-in-Charge” Reference to “Designated Representative-in-Charge – Amend Business and Professions Code § 4101
- (4) Establish a Temporary License Fee for Wholesalers – Amend Business and Professions Code §§ 4160(f) and 4161(k)
- (5) Extend Bonding Requirements for Wholesalers – Amend Business and Professions Code §§ 4162 and 4162.5
- (6) Amend Name of CPJE to Reflect Exam Requirements Specified in the Business and Professions Code – Amend §§ 4200, 4200.1 and 4200.2
- (7) Authorize the Board to Extend an Intern Pharmacist License – Amend Business and Professions Code § 4208
- (8) Authorize Citation and Fine Authority for Repositories for Redistribution of Unused Medication (as authorized by SB 798, Chapter 444, Statutes of 2005) – Amend Business and Professions Code §§ 4314 – 4315

6. Enrolled Legislation Impacting the Practice of Pharmacy or the Board’s Jurisdiction

Bills with Positions Taken by the Board

- a. AB 110 (Laird) Drug Paraphernalia: Clean Needle and Syringe Exchange Projects
- b. AB 249 (Eng) Licensees: Healing Arts: Settlement Agreements
- c. AB 543 (Plescia) Ambulatory Surgical Centers: Licensure
- d. AB 1025 (Bass) Professions and Vocations: Denial of Licensure
- e. SB 472 (Corbett) Prescription Drugs: Labeling Requirements
- f. SB 606 (Scott) Pharmaceutical Information: Clinical Trial Data
- g. SB 615 (Oropeza) Pharmacy Technicians: Scholarship and Loan Repayment Program
- h. SB 966 (Simitian) Pharmaceutical Drug Disposal

Public Comment

7. First Quarterly Report on Committee Goals for 2007/08

II. New Business/Agenda Items for Future Meetings

4:00 p.m.

PUBLIC MEETING OF THE LEGISLATION AND REGULATION COMMITTEE

4:05 p.m.

(or upon recess of the Board Meeting)

(See Attached Agenda)

The Legislation and Regulation Committee is having this public meeting to seek requests for legislative and regulatory changes for 2008. The committee requests that the proposals be provided in writing with supporting documentation. Written proposals are also encouraged from persons unable to attend this meeting.

Thursday, October 25, 2007

III. Closed Session

8:00 a.m.

The board will convene in closed session pursuant to Government Code section 11126(c)(1) to discuss and evaluate the administration of the pharmacist licensure examination. Also, the board will move into closed session pursuant to Government Code section 11126(c)(3) to deliberate on disciplinary matters.

IV. Committee Reports And Action

(Continued from October 24, 2007)

A. Organizational Development Committee

9:15 a.m.

Report and Action of Items Discussed at the Organizational Development Meeting of October 16, 2007

1. Budget Update/Report
 - a. Final Budget Report for 2006/07
 - b. Budget for 2007/08
 - c. Fund Condition Report
 - d. Implementation of the Proposed New Fee Schedule
 - e. Reimbursement to Board Members
 - f. Cashiering Update
 - g. I-Licensing Progress
2. Recognition Program of Pharmacists Who Have Been Licensed 50 Years
3. Development of a Recognition Program for Pharmacist Preceptors
4. Personnel Update
 - a. Staff Changes
 - b. Inspector and Supervising Inspection Examinations
 - c. Required EEO Training for Board Members
 - d. Privacy Training for Board Members
5. Report on the NABP District 7 and 8 Meeting
6. Meeting Summary
7. First Quarterly Report on the Committee's Goals for 2007/08
8. Approval of Full Board Minutes of July 23 and 25, 2007

Public Comment

V. Enforcement Workshop

9:45 a.m.

Staff will present information about the board's administrative and disciplinary processes, including the Administrative Procedure Act which governs the disciplinary process.

Public Comment

Lunch

VI. Petition for Reinstatement

1:00 p.m.

Mary French

VII. Closed Session

At the close of the hearing, the board will move into closed session pursuant to Government Code section 11126(c)(3) to deliberate on the request for reinstatements.

Adjournment

3:00 p.m.



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LEGISLATION AND REGULATION COMMITTEE

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Opportunities are provided to the public to address the board on each open agenda item. Board members who are not on the committee may attend the meeting as observers.

Agenda

DATE: October 24, 2007

**PLACE: San Jose DoubleTree Hotel (near San Jose Airport)
2050 Gateway Place
San Jose, CA 95110
(408) 453-4000**

Wednesday, October 24, 2007

A. CALL TO ORDER

***4:05 p.m.**

B. Requests for Legislative and Regulatory Proposals for 2008

1. Previously Discussed Proposed Legislation

- a. Immunizations by Pharmacists Pursuant to Published Recommendations of the Advisory Committee on Immunization Practices – B&PC 4052.8
- b. Furnishing Dangerous Drugs During an Emergency – B&PC 4062
- c. Temporary Permit for Damaged Pharmacies – B&PC 4110

2. Proposed Legislation

- a. Who May Order Dangerous Drugs or Devices, Exceptions (technical change) – B&PC 4059.5
- b. PIC reporting requirements – B&PC Sections 4101, 4113 & 4305
- c. Amendment Furnishing Dangerous Drugs by a Pharmacy – B&PC 4126.5
- d. Requirements for Renewal of Pharmacist License involving CE– B&PC 4231
- e. Entry Into Pharmacists Recovery Program, Administrative Fee - B&PC 4362
- f. Controlled Substance Utilization Review and Evaluation System, Clinic Reporting – H&SC 11165
- g. References Update for statutory medications referencing B&PC 4052

**Times are approximate and are subject to change
Committee materials will be available on the board's Web site by October 17, 2007.*

3. Proposed Regulations

- a. Graduate of Foreign Pharmacy Schools (technical change) – 16 CCR 1720.1

C. Public Requests for Future Legislation and Regulatory Proposals

The public is encouraged to bring to the meeting copies of proposed language, an explanation of the problem, and how the proposed language would correct the problems.

Adjournment

5:15 p.m.